**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF NORTH CAROLINA**
**STATESVILLE DIVISION**

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

**CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV**

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant
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MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

**PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF JANICE CONNOR TAKEN AUGUST 13/14, 2013**

| BSC Designation | Objection | Plaintiffs Counter Designation |
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| jc081413, (Pages 464:8 to 475:22)<br><br>6 Q. Since you've been in the position in women's<br>7 health, has Boston Scientific funded and supported<br>8 clinical research related to its sling medical devices<br>9 to treat stress urinary incontinence?<br>10 A. So since I started in 2009, we have had a very<br>11 robust program for managing ISRs, which are<br>12 investigator-sponsored research studies. So these are<br>13 the funded studies that Boston Scientific provides<br>14 dollars for to independent researchers. So we've had a | 467:6-16<br>FRE 403 confusing and misleading | |

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| 15 robust program since 2009 that continues today with<br>16 increased funding through the years.<br><br>***<br>jc081413, (Pages 467:17 to 468:3)<br>467<br>17 Q. And then same question with regard to Boston<br>18 Scientific's products to treat pelvic organ prolapse,<br>19 the Pinnacle and Uphold lines.<br>20 Since you've been in the director of clinical<br>21 programs, has Boston Scientific funded and supported<br>22 clinical programs to investigate those products?<br>23 A. For pelvic organ prolapse?<br>24 Q. Yes.<br>468<br>1 A. Absolutely. So there are approximately nine<br>2 active studies right now with many of those studies on<br>3 the pelvic organ prolapse products.<br><br>***<br>15 Q. I want to talk about the medical devices that<br>16 you've been involved with in women's health to treat<br>17 stress urinary incontinence, Boston Scientific slings.<br>18 What are those devices?<br>19 A. So for our slings right now we have Advantage<br>20 sling, we have Lynx, Prefyx, Obtryx, and Solyx.<br><br>***<br>16 Q. For all of those devices, the sling devices<br>17 that you mentioned and the treatments, the medical<br>18 devices to treat pelvic organ prolapse, were those<br>19 cleared by the FDA prior to you coming into the women's<br>20 health division?<br>21 A. When I started in April '09, all of those<br>22 devices were currently on the market. | 467:17-468:3<br>FRE 401, 402, 403<br><br>474:15-20<br>FRE 403 confusing and misleading<br><br>475:16-22<br>FRE 401; 403 Irrelevant and misleading reference to FDA | |

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| jc081413, (Pages 476:1 to 478:2)<br><br>Are there studies in the published literature on all of Boston Scientific slings and pelvic organ prolapse medical devices?<br>A. Yes, there are. So one of my responsibilities is to monitor that literature. So there are today over 50 studies published on our stress urinary incontinence devices as well as our pelvic organ prolapse kits.<br>Q. And for each one of the devices that we mentioned, are there studies looking -- clinical trials, clinical studies looking at the safety and effectiveness of each one of those devices?<br>A. Absolutely. So a lot of these studies, as I was explaining, for research they have -- they might have different objectives, so they might be studying these devices in a certain patient population. I know there's a study on women who are traumatized. There's a study published on sexually traumatized women. And they were using the device as -- that's an example of a certain population. They have studies on patients who have had previous failures for these devices.<br>477<br>So there are many studies of different patient populations, but they're all on the overall outcomes, which include the safety and effectiveness.<br>Q. So for each one of Boston Scientific's | 476:4-477:8<br>FRE 403<br>Confusing and misleading | |

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| 5 slings -- Advantage, Lynx, Prefyx, Obtryx, and Solyx --<br>6 are there clinical studies looking at the safety and<br>7 effectiveness of each one of those devices?<br>8 A. Yes, there are.<br><br>***<br><br>15 Q. And are there multiple studies looking at the<br>16 safety and effectiveness of these slings and these<br>17 treatments for pelvic organ prolapse?<br>18 A. Correct. So we do have on file at Boston<br>19 Scientific a list of these studies. There are -- again,<br>20 they're included in our clinical documents to summarize<br>21 the safety and effectiveness of these devices. We also<br>22 use these studies to support these products for other<br>23 country approvals. So we do have many studies on file<br>24 in-house that we monitor that are published. | 477:15-24<br>FRE 401; 403<br>Irrelevant and misleading reference to foreign regulatory process. Misleading and confusing as it coflates POP and SUI devices. | |
| jc081413, (Pages 495:10 to 498:18)<br>495<br>10 Q. Now, I want to talk about the Uphold device,<br>11 Boston Scientific's Uphold device that's used to treat<br>12 pelvic organ prolapse.<br>13 What is Exhibit 534?<br>14 A. Exhibit 534 is a published study in the journal<br>15 of international urogynecology in 2012 by Dr. Vu and his<br>16 coauthors of 115 patients. And this was at a single<br>17 center. This is in Chicago, Illinois. These patients<br>18 were treated with the Uphold device and were followed --<br>19 I believe they're followed out to a year at a minimum.<br>20 And they reported on their anatomic outcomes.<br>21 He also had collected data on quality-of-life, which we | | *jc081413, (Pages 549:17 to 550:5)*<br>*549*<br>*17 Q. Now, take out 534. This is a study titled*<br>*18 "Minimal mesh repair for apical and anterior prolapse*<br>*19 initial anatomical and subjective outcomes."*<br>*20 A. Correct.*<br>*21 Q. And among the authors on that study is a*<br>*22 Dr. Vu.*<br>*23 A. Vu.*<br>*24 Q. Vu out of Fort Worth?*<br>*550*<br>*1 A. Yes.*<br>*2 Q. And the last author listed is*<br>*3 Roger P. Goldberg, who we've talked about a lot.*<br>*4 Correct?* |

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| 22 talked about before. So one of those questionnaires was<br>23 the pelvic floor distress inventory, which again<br>24 patients record information on how their pelvic floor<br>496<br>1 disease basically impacts their daily life.<br>2 They also had completed a questionnaire called<br>3 the "surgical satisfaction questionnaire," which<br>4 includes questions about will they recommend the surgery<br>5 to their friends, to their mothers, daughters, and would<br>6 they do the surgery again.<br>7 Q. And what did the results from those --<br>8 collecting that data on quality-of-life, what was that?<br>9 A. So what the results show that 93 percent of the<br>10 women who completed the surgical satisfaction<br>11 questionnaire reported they were satisfied and they<br>12 would choose the surgery again.<br>13 Q. Did the study look at rates of mesh exposure?<br>14 A. They did. So they did measure rates of mesh<br>15 exposure. So the rate in this clinical study was<br>16 2.6 percent.<br>17 Q. Finally, could you read the author's conclusion<br>18 in the abstract there.<br>19 A. Sure. "This technique resulted in successful<br>20 outcomes within both anterior and apical compartments<br>21 with a low rate of mesh complications, and no cases<br>22 requiring mesh removal or hospital readmission. High<br>23 rates of satisfaction and improved condition-specific<br>24 quality-of-life were observed."<br>497<br>1 Q. And those are good results and good<br>2 conclusions?<br>3 A. Those are good results, yes.<br>4 Q. And do you agree that the author's conclusions | 497:4-14 | *5 A. Correct.* |

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| flow from the data that they collected in the study?<br>A. I do agree. So he had actually also looked at<br>patients who've had a uterus and who had a previous<br>hysterectomy, so patients without a uterus and those who<br>do. And their rates are over 95 percent for their<br>anatomic success. So that is very positive data.<br>Q. And does this study establish that Boston<br>Scientific's Uphold device is a safe and effective<br>option?<br>A. It does. Absolutely.<br>Q. And are there other published studies that look<br>at the Uphold -- Boston Scientific's Uphold device?<br>A. There are, yes.<br>Q. And are those studies published?<br>A. There are. There are many more upcoming<br>studies ongoing now and that are in the process of being<br>printed.<br>Q. Are there other studies that look at the Uphold<br>device that establish that it's a safe and effective<br>option?<br>498<br>A. Yes, there are.<br>Q. Has Boston Scientific stopped studying its --<br>these devices, these slings and POP devices?<br>A. No. So we have -- as I mentioned before, that<br>robust ISR program, so that is still ongoing.<br>We've just approved recently over $2 million<br>grant for a research trial on Uphold LITE. So that is<br>ongoing.<br>There are many other studies on Uphold. For<br>example, there's a Pinnacle study ongoing as well. We<br>have a Solyx study that's being presented -- I think I<br>mentioned that -- in the fall.<br>We also have three very large studies, over 400 | FRE 401; 402; 403; 701; 702.<br><br>497:15-498:1<br>FRE 401, 402, 403, 701, 702<br>Confusing and Misleading<br><br>498:2-18<br>FRE 401; 403<br>Ongoing clinical trials and recently funded clinical trials on other products are irrelevant to BSC's conduct in 2010 regarding the Uphold. | |

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| 14 patients each, that will be -- one just started in the<br>15 Solyx sling with the Obtryx sling. That study started<br>16 and will go on for many years, outwards of five years.<br>17 And there's an Uphold study and there's a Xenform study.<br>18 So no. There's many studies ongoing now. | | |
| jc081413, (Pages 498:23 to 499:3)<br>498<br>23 Q. Are there published studies, some that we've<br>24 looked at and others, that establish that Boston<br>499<br>1 Scientific's Pinnacle and Uphold devices are safe and<br>2 effective options?<br>3 A. Yes. | 498:23-499:3<br>FRE 401; 402, 403, 701;702 | |
| jc081413, (Pages 501:5 to 503:5)<br><br>20 Q. And then if there are individual reports, will<br>21 Boston Scientific get those and report those to the FDA<br>22 if that's -- if they qualified under the FDA<br>23 regulations?<br>24 A. Yep. That's correct. | 502:20-24<br>FRE 401; 403<br>Irrelevant FDA reference | |
| jc081413, (Page 567:1 to 567:14)<br><br>1 Q. The studies that you talked about to the jury<br>2 that we marked as exhibits, do you personally believe<br>3 those studies support the safety and effectiveness of<br>4 Boston Scientific's SUI and pelvic organ prolapse<br>5 devices?<br>6 A. I do. | 567:1-6<br>FRE 401; 402; 403; 701;702 | |

DATED: June 26, 2015

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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